DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-503/S-039

3M Pharmaceuticals
3M Center Building 270-3A-08
St Paul, MN 55144-1000

Attention: Tamara Hetrick
Manager, Regulatory Affairs

Dear Ms. Hetrick:

Please refer to your supplemental new drug application dated, March 4, 2009, received March 10, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Proventil HFA (albuterol sulfate) Inhalation Aerosol.

This "Changes Being Effected" supplemental new drug application provides for changes in the Patient's Instruction for Use section in step # 6 to read "If your physician has prescribed additional puffs, wait 1 minute, shake the inhaler again, and repeat steps 3 through 5. Replace the cap after use".

We have completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the submitted labeling (package insert) submitted December 1, 2008. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 20-503/S-039.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Angela Robinson, Regulatory Project Manager, at (301) 796-2284.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary Allergy Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Approved Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20503	SUPPL-39	3M PHARMACEUTICALS INC	PROVENTIL-HFA

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ANGELA H ROBINSON
09/08/2009

BADRUL A CHOWDHURY
09/08/2009